federal register

THURSDAY, DECEMBER 22, 1977
PART III

CONSUMER PRODUCT SAFETY COMMISSION

■

TECHNICAL REQUIREMENTS FOR DETERMINING SHARP POINTS IN TOYS, AND OTHER ARTICLES INTENDED FOR USE BY CHILDREN UNDER 8 YEARS OF AGE

[6355–01]

Title 16—Commercial Practices

CHAPTER II—CONSUMER PRODUCT SAFETY COMMISSION.

SUBCHAPTER C—FEDERAL HAZARDOUS SUBSTANCES ACT REGULATIONS

PART 1500—HAZARDOUS SUBSTANCES AND ARTICLES; ADMINISTRATION AND ENFORCEMENT REGULATIONS

Final Technical Requirements for Determining a Sharp Point in Toys and Other Articles Intended for Use by Children Under 8 Years of Age

AGENCY: Consumer Product Safety Commission.

ACTION: Final regulation.

SUMMARY: The Commission is issuing a regulation which establishes technical requirements for toys and articles intended for use by children under 8 years of age. These requirements identify sharp points on such articles that could injure children. If the Commission identifies sharp points on particular children's articles that present an unreasonable risk of injury to children under 8 years of age, it will initiate rulemaking proceedings to ban those articles.

DATES: The regulation becomes effective on December 22, 1978, and it applies to all products subject to the regulation and introduced into interstate commerce after that date.

FOR FURTHER INFORMATION CONTACT:

Elaine Besson, Office of Program Management, Consumer Product Safety Commission, Washington, D.C. 20207, 301–492–6453.

SUPPLEMENTARY INFORMATION:

Background

On January 7, 1975, the Consumer Product Safety Commission, pursuant to section 2(f)(1)(D) of the Federal Hazardous Substances Act (FHSA, 15 U.S.C. 1261(f)(1)(D)), proposed for public comment regulations to ban toys intended for children under 8 years of age[1] that present an unreasonable risk of personal injury from puncture or laceration hazards due to sharp points (40 FR 1491). The proposed regulations included test criteria for determining whether such toys present these hazards.

Following extensive review of the public comments received, as well as staff reevaluation of the proposal, the Commission withdrew the January 1975 proposal and proposed a new regulation for public comment on August 4, 1977 (42 FR 39648–56).

The primary reason for proposing a new regulation in August 1977 was that the Commission decided not to pursue a regulation of sharp points on toys that automatically banned all toys not meeting specified technical criteria. Accordingly, the August 1977 proposed regulation was designed to identify toys containing sharp points that the Commision preliminarily believed to be hazardous to children under 8 years of age, but not to ban them automatically.

The final regulation issued below, like the August 1977 proposal, is a technical requirements regulation which preliminary identifies hazardous toys. The Commission will regulate those toys on a product-by-product basis whenever it believes that they present a mechanical hazard, as defined in the FHSA.

The August 1977 proposal also contained some technical changes that were made to the test method of the January 1975 proposal, including a new set of articulated probes to determine accessibility of sharp points, a new dimension for the slot in the sharp point test device, and a maximum application force for the test procedure. All of the changes were fully discussed in the August 4, 1977 Federal Register document. The provisions of the August 4, 1977 proposal are fully discussed below.

Proposed Regulation

(a) Risk of Injury

In issuing the proposed regulation, the Commission found that certain toys intended for children under 8 years of age can puncture or lacerate skin and cause bleeding, during normal use or reasonably foreseeable misuse, and thus present an unreasonable risk of injury. This finding was based in part on the staff's investigation of the sharp points present on such toys that have been in the marketplace during the past few years.

In addition, the Commission relied on an analysis of toy-related injuries contained in its in-depth investigation reports and reported through its National Electronic Injury Surveillance System (NEISS). NEISS is a computer-based network of 119 statistically-selected hospital emergency rooms throughout the country which transmits injury data to the Commission.

Unlike the in-depth reports, NEISS reports do not distinguish between product-caused and product-related injuries and do not clarify whether an injury resulted from the normal use or from the reasonably foreseeable misuse of a product. However, NEISS surveillance data provide important information on the type and severity of injuries and the ages of those being injured.

A review of NEISS injury data indicates that a substantial number of children under 8 years of age receive laceration and puncture injuries in toy-related incidents. In calendar year 1976, for example, an estimated 43,300 children in that age category were treated in hospital emergency rooms for toy-related injuries.

To determine the extent to which lacerations and punctures occur from toys intended for childen under 8 years of age, the Commission staff divided toys into the following three categories:

(a) Toys primarily intended for use by children under the age of 8 years.

(b) Toys primarily intended for use by children 8 years to 14 years of age.

(c) Toys intended for use by children in both age groups.

Of the estimated 43,300 injuries treated in emergency rooms in 1976, an estimated 9,000 were associated with products intended primarily for use by children under 8 years of age. An additional 30,800 injuries were associated with products intended for use by children in both the under-8-year and the 8-to-14-year age groups. In addition, based on NEISS estimates, laceration and puncture injuries accounted for over half (approximately 53 percent) of all toy-related injuries to children under 8 years of age.

By definition, the NEISS-reported injuries which support the need for the technical requirements are serious enough to be treated in hospital emergency rooms. A purchaser of toys for children under 8 years of age certainly does not expect them to cause such injuries to children. While many toy-related puncture and laceration injuries may be scratches and finger prickings causing minor bleeding, there are a substantial number of injuries which are more severe. Such injuries warrant the adoption of reasonable regulations to reduce or eliminate their occurrence.

In the proposal, the Commission emphasisized that the proposed technical requirements were intended to set a standard of safety to reduce the risks of injury not only for the products currently available to young children, but also for the new and redesigned products for which there are no hazard experience data available to the Commission. The Commission estimates that between 3,000 and 5,000 new children's products (of which a large number are intended for children under 8) are introduced into the marketplace each year.

(b) Procedures

On August 4, 1977 the Commission proposed a technical requirements regulation that established criteria for sharp points on toys intended for children under 8 years of age, but did not ban automatically toys failing to meet those criteria. Under this approach, the Commission would regulate such toys on a product-by-product basis whenever they both failed to meet the test criteria and presented a mechanical hazard as defined in the FHSA, in the judgment of the Commission. (The reasons supporting this approach are detailed in the August 4, 1977 Federal Register document.)

If the Commission decided to initiate banning actions against any toys found to be out of compliance with the technical requirements, it could proceed in a few different ways. Under relevant provisions of the Administrative Procedure Act (5 U.S.C. 553), which govern regulations issued under sections 2(f)(1)(D) and 3(e) of the FHSA (unless the Com-

[1] The Commission intends that the scope of the technical requirements regulation issued below will include other articles intended for use by children under 8 years of age, as well as toys. However, in an effort to simplify reading the preamble, the term toy(s) hereafter will be used inclusively for both toys and other articles intended for use by children.

mission specifically selects alternative procedures), the Commission cannot ban a toy until it publishes a general notice of proposed rulemaking in the FEDERAL REGISTER. In the alternative, persons subject to the proposed rule could be named and either personally served or otherwise have actual notice of it (5 U.S.C. 553(b)).

Depending upon the individual circumstances of a potential banning situation, the Commission will decide how best to provide the required prior notice to manufacturers and others who are subject to a toy banning regulation. If the timing of a ban is a crucial factor, the Commission may decide that individualized notice to those subject to the proposed rule will best protect the public. Alternatively, if comment from consumers and other members of the public is considered particularly important, the Commission would probably publish a notice in the FEDERAL REGISTER and accept comments for a specified time period.

It may even be that the Commission would first notify manufacturers of a toy that has failed the test criteria before deciding whether to solicit public comment in a FEDERAL REGISTER banning proposal. All of these options will be open to the Commission when it discovers that a particular toy does not meet the technical requirements and when it decides preliminarily that such a toy presents a mechanical hazard under the FHSA.

In whatever manner the Commission provides the necessary notice of a proposed ban, a toy is not banned unless and until the Commission issues a final regulation classifying the toy as a hazardous substance (and thus a banned hazardous substance) according to sections 2(f)(1)(D), 2(q)(1)(A), and 3(e) of the FHSA.[2] If the Commission decides that a toy that fails to meet the technical requirements nevertheless does not present a mechanical hazard, the Commission will not initiate action against that toy.

(c) SHARP POINT TEST CRITERIA

The sharp point test criteria in the August 1977 proposal relied, to a large extent, on a test device that the National Bureau of Standards (NBS) developed for the Commission. NBS designed this sharp point test device to distinguish, on the basis of sharpness, between the sharp and dull points that children can contact during the casual handling of toys. Casual handling includes the range of activity associated with unpacking, handling, operating, and playing with toys, including foreseeable misuse and other types of play not intended by the manufacturer.

In determining the sharpness of various points to develop the tester, NBS considered data from three sources:

i. Subjective evaluation by 50 adult males and 50 adult females (nonphysicians) of the sharpness of a set of manufactured conical metal points. The 100 adults rated each point as either too sharp, intermediate, or sufficiently dull for use in children's toys under casual handling conditions.

ii. Subjective evaluation by 37 physicians of a similar set of conical points. The physicians rated each point as acceptable or unacceptable for use in children's toys under casual handling conditions.

iii. Actual skin puncture tests performed with the metal points used in the subjective evaluation tests. The skin puncture tests, performed on both human cadaver skin and pigskin samples, were designed to determine what combinations of force and point configuration are necessary to cause punctures that penetrate human skin.

The results from the two groups in the subjective evaluation tests and the results of the skin puncture tests indicated a similar demarcation between sharp and dull points. From these results, NBS developed a sharp point tester capable of judging the sharpness of a point of any shape based on its penetration into a gaging slot of specified width, length, and depth. The gaging slot measures 0.040 inch in widths, 0.045 inch in length and 0.020 inch in depth.

NBS also incorporated as part of the test procedure a 0.5-pound spring which a test point must override before an indication is made that the point is sharp. NBS determined that if a point was flexible and could not retain its shape under a force of 0.5 pound, the point would be incapable of puncturing skin.

The proposed test method also provided that no more than 1.0 pound of force could be applied to a point when it is inserted into the gaging slot of the tester. The purpose of this maximum application force is to preclude a false indication of sharpness occurring from a point that is shaved or extruded into the slot. This could occur when a point's configuration barely prevents it from entering the slot far enough to fail the test criteria.

The testing criteria in the August 1977 proposal involved testing for sharp points before and after application of the Commission's "use and abuse" test procedures (16 CFR 1500.50–53). These test procedures are intended to expose potential hazards that could result from normal use or the reasonably foreseeable damage or abuse to which toys and games are subjected.

The Commission has concluded that, pending additional staff review, the bite test provisions in the use and abuse regulations (16 CFR 1500.51(c), 1500.52(c), and 1500.53(c)) should not be incorporated into the sharp point test criteria. The August 1977 proposal reflected this conclusion.

(d) ACCESSIBILITY CRITERIA

The August 1977 proposal included criteria for determining when a sharp point was sufficiently accessible to present a hazard to children under 8 years of age. Any point that was inaccessible would not fail to meet the criteria, even if it would be considered sharp by the sharp point test device.

The proposal specified two articulated probes that were intended to determine accessibility of children's fingers to potentially hazardous points. The Commission selected the anthropometric measurements[3] of young children for the lengths and the diameters of the small and middle fingers as well as the dimensions for hand clearance. Because children up to the age of 8 years are in a period of rapid growth, the anthropometric measurements were divided into two age groups—0 to 3 years and 3 years to 8 years of age. The two probes correspond to these same age groups.

To insure protection of the greatest number of children in each age group, the Commission selected anthropometric measurements that reflect the following assumptions:

(i) That the younger children in each age group have narrower hands and therefore can reach into openings which would be inaccessible to an older child.

(ii) That the older children in each age group have longer fingers and therefore can touch the inside components of toys which would be inaccessible to a younger child.

Furthermore, anthropometric data are not available for the dimensions of a child's index finger. Those dimensions have been approximated by averaging the respective dimensions of the small and middle fingers of children in the two age groups.

In the 0- to 3-year age group, measurements for a fifth-percentile[4] 3-month-old's small and middle fingers were averaged and used to approximate the diameter of the index finger. Measurements for a 95th-percentile[5] 3-year-old's small and middle fingers were averaged and used to approximate the length of the index finger. The minimum hand-clearance measurement of a fifth-percentile 3-month-old child was selected. These measurements were then used to define the dimensions of probe A.

Similarly for the 3-year to 8-year age group, measurements for the small and middle fingers of a fifth-percentile child 37–42 months of age were averaged to approximate the diameter of the index finger. Measurements for the small and middle fingers of a 95th-percentile child 85–96 months of age were averaged and used to approximate the length of the index finger. The minimum hand-clear-

[2] An exception is that, under section 3(e)(2) of the FHSA (15 U.S.C. 1262(e)(2)), a toy presenting an "imminent hazard" may be banned immediately by publication of a single notice in the FEDERAL REGISTER.

[3] All measurements were obtained from the University of Michigan's study, "Physical Characteristics of Children as Related to Death and Injury for Consumer Product Design and Use," Highway Safety Research Institute, The University of Michigan, Ann Arbor, Mich. 48105.

[4] A fifth-percentile 3-month-old child represents a child this age who is smaller than 95 percent and larger than 5 percent of children the same age.

[5] A 95th-percentile 3-year-old child represents a child this age who is larger than 95 percent and smaller than 5 percent of children the same age.

ance dimensions for a fifth-percentile child 37–42 months of age were selected. These dimensions were then used to define the dimensions of probe B.

Probe A determined the accessibility of points in holes, recesses, or openings on toys intended for children 3 years of age or less. Probe B determined the accessibility of points in holes, recesses, or openings on toys intended for children over 3 years up to 8 years of age.

Based on staff recommendations and the anthropometric measurements from the University of Michigan study on the physical characteristics of children (cited in footnote 2, above) in the two age groups, the Commission defined accessibility for holes, recesses, and openings on toys and other children's articles as follows:

(1) *Finger access.* Section 1500.48(c)(3)(i) of the proposed regulation provided that access into openings which are large enough to accept a child's finger but too small to accept a child's hand would be determined by the appropriate accessibility probe.

Each of the two joints on a probe could be rotated up to 90 degrees to simulate knuckle movement and the total depth of insertion for accessibility would be up to the collar on the probe that is appropriate for either the 0- to 3-year age group (probe A) or the 3-year to 8-year age group (probe B).

The diameter of the collar on each probe was representative of the hand-clearance diameter of a fifth-percentile child in the youngest age category within each age group. For the 0- to 3-year age group, the youngest age category is 0–3 months of age and for the 3-year to 8-year age group, the youngest age category is 37–42 months of age.

(2) *Hand access but not shoulder access.* Section 1500.43(c)(3)(ii) of the proposed regulation provided that access into openings large enough to accept a child's hand and arm but too small to admit the child's torso (body trunk) would be determined by the dimensions of the entrance of the opening. Such openings include openings that are larger than the width of a child's hand but smaller than the breadth of a child's shoulders. The Commission proposed that a depth-of-insertion factor of two and one-quarter multiplied by the minor dimension of an opening be used to determine the accessibility of points in such openings.

The Commission defined a minor dimension of an opening as the diameter of the largest sphere that will pass through the opening, and it could be determined by using a pair of calipers. This dimension, multiplied by two and one-quarter, determined the maximum depth of insertion for accessibility.

The value of two and one-quarter is the approximate average of the ratio of arm length to shoulder breadth for a 50th-percentile child in each of the two age groups. For example, the depth of insertion into an opening with a minor dimension slightly smaller than the breadth of a child's shoulders will be slightly less than the length of the child's arm.

(3) *Total accessibility.* The Commission proposed that openings larger than the breadth of a child's shoulders should be considered totally accessible.

For the 0- to 3-year age group, the Commission selected a shoulder breadth measurement of 7.36 inches. This measurement represents a fifth-percentile one-year-old child, since children who are under one-year of age are less mobile and therefore are less likely to climb into cavities than children who are one year of age or older.

For the 3-year to 8-year ago group, the Commission selected a shoulder breadth measurement of 9.00 inches. This measurment represents a fifth percentile child in the age category of 37–42 months.

The Commission proposed that, for toys intended for children 0 to 3 years of age, access into openings with a minor dimension of 7.36 inches or larger would be considered totally accessible to a child. For toys intended for children 3 years to 8 years of age, access into openings with a minor dimension of 9.00 inches or larger would be considered totally accessible to a child. Because openings that are totally accessible to children in the 0–8 years of age span may contain smaller openings that are not totally accessible to such children, access into these smaller openings would be determined by the appropriate procedures explained above.

(4) *Inaccessible points.* From the results of sharp point tests conducted on a representative sample of toys, the Commission observed that tabs, wires, and other protrusions do not present a puncture or laceration hazard if such protrusions are flush with a protecting surface which is part of the toy. The Commission therefore decided that a point should be considered inaccessible if it is protected by an adjacent surface and any gap between the point and the adjacent surface does not exceed 0.020 inch.

(e) EXEMPTIONS

The proposed regulation exempted baby cribs and bicycles that are the subject of safety regulations already issued by the Commission under the FHSA (see 16 CFR 1500.18(a)(12), (13), and (14); 16 CFR Parts 1508, 1509, and 1512). These children's products, because they have already been addressed by the Commission in specific regulations, did not need to be addressed by the generic safety requirements for sharp points.

Although the Commission had considered whether other children's products should be exempted from coverage, it decided in issuing the proposal that no other such exemptions were necessary or appropriate. Of course if any toy or children's article intended for children under 8 does not comply with the technical requirements but does not present a hazard, the Commission would not initiate any banning action against such an article.

The Commission included in the proposed technical requirements an exemption for children's products that have sharp points by reason of their functional purpose (and that do not have any nonfunctional sharp points). Toys with functional sharp points, such as needles for toy sewing machines, were exempted as long as the toy was identified by a conspicuous, legible, and visible label as having a sharp point(s). Other children's articles with functional sharp points, such as the tips on writing instruments, were exempted and did not require any labeling.

In addition, the Commission discussed the applicability of the regulation to model and craft kits. Most children under 8 years of age do not have the dexterity and the reading ability necessary for assembling complicated model and craft kits, and such products in the marketplace today are usually not intended for children in the under-8 age category. Therefore, the Commission clarified that model and craft kits were excluded from the scope of the proposed regulation.

(f) PREEMPTION

Whether a technical requirements regulation would preempt a state or local regulation that applies to sharp points on toys is a crucial issue. However, it is possible that the Commission's interpretation of the FHSA's preemption provision would not affect resolution of this question if a dispute arose. For example, if a state banned a toy and the manufacturer of the toy claimed that the state's authority was preempted by the existence of the Commission's regulation, the Commission would not necessarily be a party to any litigation or any out-of-court negotiation which might occur.

Nevertheless, the Commission interpreted the FHSA preemption provision (section 18 of the FHSA) and stated its view of how that provision would apply to a technical requirements regulation established to protect against the hazard of sharp points on toys intended for children under 8 years of age. The Commission's position, as stated in the August 4, 1977, FEDERAL REGISTER document, was that state and local governments would be prohibited from establishing or enforcing any nonidentical requirement that addresses the hazard of sharp points on toys intended for children under 8.

The Commission's proposed regulations are technical requirements that establish technical criteria for toys intended for children under 8. As long as states or local governments use these same criteria to regulate such toys, their requirements would be considered to be identical to the Commission's requirements, and thus not prempted according to the Commission's stated view of the preemption provision.

Even if a state or local government were to impose different penalties or use different procedures to regulate toys, there would be no preemption as long as the technical criteria were identical. As an example, if a state were to ban automatically any toy not meeting the criteria, such a ban would not be preempted by the Commission's technical require-

ments, according to the position taken by the Commission when it proposed the requirements in August.

(g) EFFECTIVE DATE

The regulation was proposed to become effective 365 days after its publication in final form in the FEDERAL REGISTER, and to apply to all products introduced into interstate commerce after that date.

The Commission further proposed that introduction into interstate commerce, for purposes of the regulation, be defined as follows: A toy manufactured outside the United States is introduced into interstate commerce when it is first brought within a U.S. port of entry. A toy manufactured in the United States is introduced into interstate commerce (a) at the time of its first interstate sale, or (b) at the time of its first intrastate sale if one or more of its components and/or raw materials were received interstate, whichever occurs earlier.

(h) ENVIRONMENTAL CONSIDERATIONS

Before proposing the technical requirements regulation, the Commission assessed the environmental impact and concluded that no potentially significant environmental effects would be associated with the regulation. The Commission therefore found that there was no need for an environmental impact statement.

COMMENTS ON PROPOSAL

The Commission received 25 comments on its August 1977 proposal of a technical requirements regulation. Twenty-one of these came from the toy industry, including comments from a large retailer, from the trade association Toy Manufacturers of America, Inc. (TMA), and from individual toy manufacturers. In addition, two individual consumers, Consumers Union, and a Johns Hopkins University epidemiologist who specializes in the prevention of injuries commented on the proposal. These comments are discussed below, according to the issues they address (the issues are categorized to correspond generally to the "Proposed Regulation" discussion of this preamble).

(a) RISK OF INJURY

One manufacturer has commented that the injury data discussed by the Commission in support of its August 1977 sharp points proposal (1) do not adequately establish that an injury problem is associated with sharp points and (2) are the same set of data that justify the Commission's proposed sharp edges regulation (published for comment in the FEDERAL REGISTER on September 1, 1977, 42 FR 44160).

In the Commission's view, the injury data indicate a need for regulation of sharp points on toys intended for children under 8 years of age. As discussed in section (a) of the "Proposed Regulation" portion of this preamble, the NEISS data, in-depth investigation reports, and staff investigation of sharp points present in toys in the marketplace during the last few years all point to the conclusion that certain toys can puncture and lacerate skin. This information must be considered with the staff's technical judgment that certain types of sharp points on toys—some 90-degree corners on sheet metal toys, for example—are hazardous to children under 8 years of age.

The Commission reaffirms its finding that certain sharp points on toys may present an unreasonable risk of injury to such children. In addition, since sharp edges on toys cause laceration injuries in much the same way that sharp points do, the same set of data is relevant to both toy regulations.

(b) PROCEDURES

The banning procedure for toys which fail to meet the criteria and which the Commission believes present an unreasonable risk of injury is discussed in section (b) under "Proposed Regulation." The procedure under the final regulation is the same as the procedure proposed in August 1977.

Before any toy can be banned, the Commission must notify those who would be affected by the ban, such as the manfacturer of the toy. TMA and numerous other industry commenters have suggested that the notification be divided into two stages. They believe that manufacturers should be guaranteed a reasonable opportunity to respond to the Commission before any proposed ban is published in the FEDERAL REGISTER.

The Commission recognizes that a publicly proposed ban could adversely affect the marketability of a product, even if a final ban is never imposed. However, this factor must be balanced against the need for expeditious banning procedures. This need can be especially important because the current procedures already require a pre-screening procedure (testing according to the technical requirements), a banning proposal, and a final ban to remove a product from the market.

Although the Commission may decide that prior notice to manufacturers of potentially hazardous toys would be fair and appropriate in particular circumstances, it does not believe that it should be restricted to this approach in all cases. If safety demands that a toy be removed from the market without any unnecessary delay, the Commission plans to notify affected persons individually or by FEDERAL REGISTER publication and then issue a final ban as soon as it has considered the comments received.

In a different comment concerning the procedures, one manufacturer has stated that a self-executing (automatic) banning regulation would be preferable to the proposed technical requirements regulation which does not distinguish between "acceptable" and "non-acceptable" sharp points on toys. If the Commission could have devised a regulation which did distinguish points in this manner, it would have issued it as a self-executing regulation. Since no available test device takes into account all of the necessary variables such as location, however, the final regulation adopts the proposed approach which permits the Commission to take such variables into account before banning any particular toy.

The Commission recognizes that, prior to final Commission banning action, the final regulation does not provide to either manufacturers or consumers positive identification of those products which may fail to meet the test criteria but which may not present an unreasonable risk of injury due to sharp points. Nevertheless, products which meet the test criteria are positively identified as not presenting a hazard due to sharp points and manufacturers can use these criteria during product design to ensure that their products will comply with the regulation.

In its comments, another toy manufacturer has suggested (1) that an evaluation of a toy which fails to meet the technical criteria take place at the Commission's regional office level to make manufacturers' involvement more convenient and (2) that Commission staff opinions on the safety of new toys be easily available. Whenever appropriate and feasible, the Commission field staff will be available to talk to manufacturers of toys which fail to meet the test criteria. In addition, the enforcement staff is always available to discuss the applicability of the criteria to new toys, although it cannot, of course, provide premarket approval of toys or of any other product.

(c) SHARP POINT TEST CRITERIA

TMA has made several comments on the sharp point test criteria proposed in August 1977. TMA has suggested and the Commission has agreed that the engineering drawings of the test device that are on file with the Commission should be specifically referenced in the regulation. This change is reflected in § 1500.48 (d) of the final regulation issued below.

TMA has also recommended that, in the interests of convenience and uniformity, the test device at figure 1 be redesigned to incorporate the 1.00 pound application force that is contained in the regulation (§ 1500.48(d)(2)(iii)). The Commission finds that the test instrument in the proposed regulation is satisfactory for its own testing purposes and will ensure that the 1.00 pound force limitation is not exceeded. If manufacturers choose to add to their test instruments a feature to register application force automatically, they are free to do so. As is stated in the regulation, any device which yields equivalent results to the test instrument shown in figure 1 may be used.

TMA has additionally suggested that the word "minimum" not be applied to the distance the sensing head is recessed in the explanation of how the sharp point test device operates (§ 1502.48(d)(1)). The Commission agrees with TMA that the inclusion of the word "minimum" which qualifies the depth of the sensing head below the face of the end cap may be confusing. Similarly, the word "maximum" which qualifies the dimensions of

the rectangular gaging slot opening of 0.040 inch by 0.045 inch, as well as the words "not more than" which qualify the 1.00 pound application force at which a point is inserted into the gaging slot, may need clarification. The Commission included these qualifiers to the opening dimensions of the gaging slot, the depth of the sensing head, and the application force to indicate to a manufacturer that these maximum dimensions, minimum depth, and maximum force represent the most stringent conditions that the Commission may use during compliance testing. To clarify these critical parameters, however, the qualifying words have been deleted from the final regulation and the following explanatory sentence has been added to § 1500.48(d)(2): "The test instruments used by the Commission in its tests for compliance with this regulation shall have gaging slot opening dimensions no greater than 0.040 inch by 0.045 inch and shall have the sensing head recessed a depth of no less than 0.015 inch. The force applied by the Commission when inserting the point into the gaging slot shall be no more than 1.00 pound."

The Commission believes that the addition of these sentences to the regulation clarifies the most stringent values for the critical parameters which define the gaging cavity of the test instrument and the application force, which may be used during the Commission's compliance tests. Manufacturers, on the other hand, if they wish to provide a margin of safety, should be sure that the gaging slot opening in their test instruments has opening dimensions of more than 0.040 inch by 0.045 inch and a sensing head depth of less than 0.015 inch. In addition, manufacturers may wish to use an application force of more than 1.00 pound. The Commission points out that manufacturers are under no obligation to perform any testing to ensure compliance with the regulation.

One manufacturer, Mattel, has also commented on certain aspects of the sharp point test criteria. In describing its own sharp point testing procedures, the manufacturer seems to suggest that its procedures would be preferable to the Commission's proposed procedures (which were developed by the National Bureau of Standards). The Commission staff was already familiar with Mattel's test procedures and had performed a comparison of the two procedures in December 1975. Although there was a high degree of correlation between the two procedures, the Commission staff found the NBS tester more repeatable, easier to use, and more helpful to designers of toys because it rated point sharpness based on the specific geometry of the point.

Mattel has suggested that the gaging slot opening dimensions in the Commission's proposed test instrument be reduced to determine the acceptability of a plastic point. If the suggestion made by this commentor were adopted as written, it would have the effect of permitting sharper plastic points on toys than would be permitted by the criteria issued below. The subject of plastic points is further discussed below in section (e) on "Exemptions".

(d) ACCESSIBILITY CRITERIA

Consumers Union (CU) has commented in some detail about the accessibility probes that are incorporated into the test criteria at § 1500.48(c), and has suggested the following:

1. Taper the finger portion of the probe (a) to correspond with the cross sectional dimensions that vary and (b) to be equated with the fifth percentile of the respective age group.

2. Taper the transition area, from the finger to the hand, to reflect more accurately the contour of the hand. CU has stated that the values of 1.02 inches and 1.51 inches (for hand clearance in the two age groups) seem to be too large for the dimension representing the region of the hand, where the third joint of the finger joins the hand.

3. Insert the probe, during testing, into the test openings with a force representative of the amount of force that children of the respective age groups may be expected to exert.

4. Articulate the probes at the junction of the finger to the hand and at the junction of the hand to the extension.

In addition, Consumers Union does not find any realistic relationship between the minor dimension of the opening multiplied by 2¼ and the depth to which a child may insert his or her fingers, hand, and arm through an opening. Practical observations by CU indicate that a 4½ year-old child could insert his or her hand and arm a distance of 9.7 inches through a 1¾-inch-wide opening and a distance of 16.5 inches, i.e. to the shoulder (torso) through a 2-inch-wide opening. Based on these observations, the multiplication factors should be 5.5 and 8.3, respectively.

CU has concluded that the probes should be revised dimensionally and, with regard to articulation, should more accurately simulate the finger, hand and arm of the respective age ranges of children. CU also believes that the probe should be inserted into openings under evaluation as far as possible, in all directions possible, and at all degrees of articulation. If force of insertion causes flexing that may expose sharp points to contact, then insertion should be made with forces suitable for each age group.

For a number of reasons, the Commission does not believe that any changes in the probes or the accessibility criteria are necessary.

The development of the accessibility probes proposed in August 1977 was conducted in response to a number of comments on the January 1975 proposal. Those comments stated that any probe should be based solely on child anthropometric data and not on data which incorporated adult dimensions.

Child dimensional data is available for the fingers, hand, and arm. However, it is intuitively obvious that children in the age range of concern, 0–8 years, become larger as they get older. Therefore, the problem of setting dimensions for accessibility is a dynamic one. One must first choose a small age range for which the dimensions are desired and then decide what percentile within that group would be appropriate. It immediately becomes apparent that for a given percentile in a body of data, thet selected dimension will increase as age increases.

With the above background points in mind, the Commission considered the problem of constructing a device which simulates the finger of a 95th percentile child. Since the device must have only one dimension each for length and diameter, it becomes necessary to select these single dimensions from the data. In order to construct the test device, the Commission made the following determination:

Only two probes should be used, one each for the age spans of 0–3 years and over 3 and up to 8 years. This was done in the interests of simplicity and economy. Rather than build 8 probes based on data at yearly increments, the Commission decided that two probes would be sufficient to cover the age ranges. The division point of three years was selected to correspond with that established in the already-issued Commission use and abuse testing procedures. To select another division point would have simply added confusion to the Commission's overall toy safety program.

The Commission believes that adoption of CU's first two suggestions would conflict with the philosophy behind the probes which is reasonable representation and simplicity. With the use of the extreme dimensions within each range there is no advantage to tapering the probes at any particular place. Tapering would not resolve the basic problem of which dimension should be required. Further, tapering the probes would add to the cost of fabrication without adding any appreciable degree of safety.

Adoption of CU's suggestion that the probe be inserted with a force appropriate to the respective age group would add substantially to the complexity of screening toys for accessible sharp points. To accomplish this suggestion would require a force transducer in series with the probe and the suspected sharp point. This is difficult and contrary to the objective of maintaining simplicity, and the suggestion is rejected.

With regard to articulation of the probe at the junction of the finger to the hand, very little safety would be gained for the added cost of fabrication and complexity. The existing probes have the capability of flexing through an arc of 180 degrees. The suggested change would add 90 degrees to this capability after certain engineering changes. In only one instance would this capability be useful. This would be an opening through which a child would curl his finger as in making a fist and then have sufficient strength left to puncture the skin. The Commission does not believe the situation occurs with frequency sufficient to justify the addition. For the same reason, the Commission is rejecting the suggestion for articulation at the wrist.

Finally, CU has contended that there is no rationale for the 2.25 multiplication factor with regard to large openings. This multiplication factor was derived from the ratio between a child's arm length and shoulder breadth and was found to be approximately 2.25 for children in any age group between 1 and 8 years of age. The Commission wishes to point out that if an opening is large enough to permit entry of a child's hand, the depth to which the child could reach would be equal to the child's arm length. However, in its efforts to derive accessibility criteria which are reasonable and which reflect the probable actions of the majority of children, the Commission believes that the location of sharp points subject to the test should be related to the size of the entrance of the opening. The Commission therefore finds that the 2.25 multiplication factor is reasonable and, in the absence of further information to guide the Commission, there is no compelling argument to change the multiplication factor to another quantity.

(e) EXEMPTIONS

Various manufacturers and TMA have supported exemptions for various products, including: Replicas of real-life devices that are neither model nor craft kits; gates or sprues on plastic toys which arise when the toys are broken off from a stringer produced in the molding process; sporting goods, camping goods, and athletic equipment; musical instruments and furniture (but not toys which are counterparts of such products); playground equipment; and kites. TMA has mentioned that its voluntary standard PS 72/76 excludes most of the above products, and has asserted that the listed products are not intended to be covered by the Commission's regulation.

The Commission, as stated clearly in the preamble to the August 1977 proposed regulation, does intend the regulation to include other articles intended for use by children under 8 years of age, as well as toys. The only intended exemptions and exclusions have been discussed in section (e) under "Proposed Regulation." If the Commission did exempt a wide variety of products, as suggested, the purpose and effectiveness of a generic regulation would be defeated. In fact, one of the reasons for changing the "self-executing" regulatory approach was to issue a broad generic regulation that regulates nearly all of the numerous products comprising the play environment of children from birth to 8 years.

The same reasoning applies to an exemption for plastic "gates" that are formed during the manufacturing process. Very often these gates are harmless, even if left untrimmed, because of their location or because they are made of soft plastic. However, if the plastic is hard and the gate is prominently exposed, lacerations or avulsions could result from use of the article by a child. The Commission would therefore use its discretion before banning any toy because of a plastic gate, and this is exactly what will occur under the "non-banning" approach embodied in the regulation issued below.

TMA has also requested that the regulation include a formal exemption procedure for future use. Since the regulation can be amended according to the informal notice and comment rulemaking procedures of the Administrative Procedure Act, the Commission intends that this would be the procedure for exempting any products it subsequently believes should be exempt from coverage. Any interested person may, of course, petition the Commission to amend the regulation to exempt products from coverage.

With regard to TMA's request for an exemption for musical instruments, the Commission believes that full-size, real-life musical instruments are not within the scope of the regulation, even though they could occasionally be used by children under 8 years of age. Therefore, no exemption for such instruments has been added. Toy musical instruments and real-life musical instruments that because of their smaller size are intended primarily for children under 8, however, are clearly within the scope of the regulation.

Finally, with regard to the functional sharp point exemption, the Pencil Makers Association, Inc. has suggested that the regulation be clarified to state specifically that a pencil is an example of an article included within the § 1500.48 (b) (2) (iii) exemption for functional sharp points. The Commission believes that such a clarification is unnecessary. The regulation already states that ballpoint pens are one example of articles that may have a sharp point but are nevertheless exempted from the regulation because the point is a functional one. Pencils would certainly be another example. By including one example, the Commission did not exclude other articles from the applicability of the functional sharp point exemption.

(f) PREEMPTION

As discussed in the preamble to the August 1977 FEDERAL REGISTER proposal and as discussed in section (f) under "Proposed Regulation" in this preamble, the Commission believes that State and local regulations would not be preempted by a technical requirements regulation, as long as they use the identical technical criteria. The use of different procedures by State and local governments, including an automatic banning approach for toys not meeting the criteria, would not change this result.

Nearly all of the industry commenters disagreed with this portion of the Commission's interpretation of the preemptive effect of the regulation issued below. They cited and discussed the legislative history of the FHSA preemption provision to show the Congressional intent that State and local governments should be prohibited from addressing the same risk of injury in a different manner than the Federal government. Chaos and a severe economic impact would result from the Commission's position, in the opinion of the industry commenters.

The Commission agrees that Congress intended manufacturers to be protected from the difficult task of complying with different manufacturing criteria in different parts of the country. As Senator Moss stated, in legislative history cited by TMA in its comments, "* * * to the extent possible, manufacturers who produce products for a national market should be required to comply with only national standards" (Cong. Record, April 28, 1976, page 56147, Column 3, Daily Edition). It is partly for this reason that the Commission interprets the FHSA preemption provision as preventing State and local governments from using non-identical technical criteria.

Under the Commission's interpretation of preemption, manufacturers can rely on the technical criteria set forth in the regulation below. No State or locality could use differing criteria to ban, because of sharp points, a toy intended for children under 8 years of age. Despite the strong and articulate comments submitted by the industry, however, the Commission still does not believe that the FHSA preemption provision prohibits States and localities from using different procedures in conjunction with the technical criteria. FHSA preemption applies only to "requirements" and the Commission's two-stage banning approach is neither included in nor required by the technical requirements regulation issued below.

Nevertheless, the Commission believes that the technical requirements regulation should not be used to ban automatically all toys not meeting the technical criteria. As a matter of public responsibility and of fairness, a regulatory body should evaluate the hazard presented by any toy which fails to meet the technical criteria before banning that toy.

The Commission's two-stage banning procedure, which provides an opportunity for considering the comments of the affected industry prior to banning, guarantees this responsibility and fairness at the Federal level. The Commission strongly encourages the use of the same or similar procedures at the State and local levels prior to the banning of any toy intended for use by children under 8 years of age that contains sharp points.

(g) EFFECTIVE DATE

The Commission has received no comments on what would be an appropriate effective date of the final regulation. As proposed, the regulation issued below will become effective December 22, 1978. All products introduced into interstate commerce after this date are subject to the regulation.

The Commission restates that, for purposes of the regulation, introduction into interstate commerce is defined as follows: A toy manufactured outside the United States is introduced into interstate commerce when it is first brought within a U.S. port of entry. A toy manufactured in the United States is introduced into interstate commerce (a) at the time of its first interstate sale, or (b) at the time of its first intrastate sale of one or more of its components and/or raw materials were received interstate, whichever occurs earlier.

(h) ENVIRONMENTAL CONSIDERATIONS

The Commission has received no comments on the environmental impact of the regulation or on its decision that there is no need for an environmental impact statement.

(i) MISCELLANEOUS

(1) TMA has suggested that the Commission reference section 2(q) of the FHSA as authority for issuing the technical requirements regulation. As TMA has pointed out, the Commission's preemption position makes clear its view that the regulation is issued for the enforcement of section 2(q). Nevertheless, the regulation is authorized by section 10(a), which authorizes regulations "for the efficient enforcement" of the FHSA, and section 2(s), which defines articles that are "mechanical hazards." Section 2(q) defines "banned hazardous substances" and the regulation issued below does not ban any product.

(2) Susan P. Baker, an Associate Professor in the Johns Hopkins University's School of Hygiene and Public Health, has commented on the scope of the regulation. She believes that the regulation should address foreseeable behavior and accidents involving high velocity impact with toys.

The Commission's view is that certain types of injuries cannot be addressed by a regulation which deals solely with the injury agent. A child who runs and falls onto any toys, or other household objects that are encountered daily, may sustain a laceration injury regardless of the shape of the toy or of the presence or absence of sharp points. By blunting or eliminating sharp points, the Commission believes that this regulation will reduce the severity of some of these types of injuries. In addition, if the Commission finds that a substantial number of additional toy-related injuries can be eliminated by further generic regulation, it will strongly consider issuing such a regulation.

(3) Two consumers have questioned the ability of the Commission to regulate effectively and the need for the proposed regulation. Despite these comments, the Commission believes that the existing hazard data support the need to reduce the potential unreasonable risk of injury associated with certain sharp points on toys. In addition, the Commission believes that the regulation issued below will be effective in setting a standard of safety for the toys intended for children under 8 years of age that are currently available and for the thousands of new such toys introduced into the marketplace each year.

FINAL REGULATION

With the exception of the minor changes discussed above, the final technical requirements regulation is identical to the August 1977 proposal. The Commission restates that English figures are used throughout the regulation. Their metric approximations are included in parentheses for convenience and information only.

Accordingly, pursuant to provisions of the Federal Hazardous Substances Act (secs. 2(s), 10(a), 74 Stat. 378 (15 U.S.C. 1261, 1269)) in accordance with the provisions of 5 U.S.C. 553, and under authority vested in the Commission by the Consumer Product Safety Act (Pub. L. 92–753, sec. 30(a), 86 Stat. 1231 (15 U.S.C. 2079(a))), the Commission amends 16 CFR Part 1500 by adding a new § 1500.48, as follows:

§ 1500.48 Technical requirements for determining a sharp point in toys and other articles intended for use by children under 8 years of age.

(a) *Objective.* The sharp point test prescribed by paragraph (d) of this section will be used by the Commission in making a preliminary determination that points on toys and other articles intended for use by children under 8 years of age, and such points exposed in normal use or as a result of reasonably foreseeable damage or abuse of such toys and articles, present a potential risk of injury by puncture or laceration under section 2(s) of the Federal Hazardous Substances Act (15 U.S.C. 1261(s)). The Commission will further evaluate points that are identified as presenting a potential risk of puncture or laceration injury to determine the need for individual product regulatory action.

(b) *Scope*—(1) *General.* The sharp point test of paragraph (d) of this section is applicable to toys or other articles that are introduced into interstate commerce on or after December 22, 1978. The sharp point test shall be applied to any accessible portion of the test sample before and after subjecting the test sample to the use and abuse tests of §§ 1500.51, 1500.52, and 1500.53 (excluding the bite test-paragraph (c) of each section).

(2) *Exemptions.* (i) Toys and other children's articles that are the subject of any of the following regulations are exempt from this § 1500.48: The regulations for bicycles, non-full-size baby cribs, and full-size baby cribs (Parts 1508, 1509, and 1512, of this chapter).

(ii) Toys that by reason of their functional purpose necessarily present the hazard of sharp points and that do not have any nonfunctional sharp points are exempt from this § 1500.48: *Provided,* Each toy is identified by a conspicuous, legible, and visible label at the time of any sale, as having functional sharp points. An example of such toys is a toy sewing machine with a needle.

(iii) Articles, besides toys, intended for use by children that by reason of their functional purpose necessarily present the hazard of sharp points and that do not have any nonfunctional sharp points are exempt from this § 1500.48. An example of such articles is a ball-point pen.

(c) *Accessibility*—(1) *General.* Any point that is accessible either before or after these tests of §§ 1500.51, 1500.52, and 1500.53 (excluding the bite test—paragraph (c) of each section) are performed shall be subject to the sharp point test of paragraph (d) of this section.

(2) *Accessible points.* (i) An accessible point for a toy or article intended for children 3 years of age or less is one that can be contacted by any portion forward of the collar of the accessibility probe designated as probe A in figure 2 of this section.

(ii) An accessible point for a toy or article intended for children over 3 years up to 8 years of age is one that can be contacted by any portion forward of the collar of the accessibility probe designated as probe B in figure 2 of this section.

(iii) An accessible point for a toy or article intended for children of ages spanning both age groups is one that can be contacted by any portion forward of the collar of either probe A or B, as shown in figure 2 of this section.

(3) *Insertion depth for accessibility.* (i) For any hole, recess, or opening having a minor dimension (The minor dimension of an opening is the diameter of the largest sphere that will pass through the opening.) smaller than the collar diameter of the appropriate probe, the total insertion depth for accessibility shall be up to the collar on the appropriate probe. Each probe joint may be rotated up to 90 degrees to simulate knuckle movement.

(ii) For any hole, recess, or opening having a minor dimension larger than the collar diameter of probe A but less than 7.36 inches (186.9 millimeters), when probe A is used, or a minor dimension larger than the collar diameter of probe B but less than 9.00 inches (228.6 millimeters), when probe B is used, the total insertion depth for accessibility shall be determined by inserting the appropriate probe with the extension shown in figure 2 in any direction up to two and one-quarter times the minor dimension of the hole, recess, or opening, measured from any point in the plane of the opening. Each probe joint may be rotated up to 90 degrees to simulate knuckle movement.

(iii) For any hole, recess, or opening having a minor dimension of 7.36 inches (186.9 millimeters) or larger when probe A is used, or a minor dimension of 9.00 inches (228.6 millimeters) or larger when probe B is used, the total insertion depth for accessibility is unrestricted unless other holes, recesses, or openings within the original hole, recess, or opening are encountered with dimensions specified in paragraph (c)(3)(i) or (ii) of this section. In such instances, the appropriate paragraphs (c)(3)(i) or (ii) of this section shall be followed. If both probes are to be used, a minor dimension that is 7.36 inches (186.9 millimeters) or larger shall determine unrestricted access.

(4) *Inaccessible points.* Points shall be considered inaccessible without testing with a probe if they lie adjacent to a surface of the test sample and any gap between the point and the adjacent surface does not exceed 0.020 inch (0.50

millimeter) either before or after the tests of §§ 1500.51, 1500.52, and 1500.53 (excluding the bite test—paragraph (c) of each section) are performed.

(d) *Sharp point test method*—(1) *Principle of operation.* The principle of operation of the sharp point tester shown in figure 1 of this section is as follows (Detailed engineering drawings for a suggested sharp point tester are available from the Commission's Office of the Secretary.): A rectangular opening measuring 0.040 inch (1.02 millimeters) wide by 0.045 inch (1.15 millimeters) long in the end of the slotted cap establishes two reference dimensions. Depth of penetration of the point being tested determines sharpness. If the point being tested can contact a sensing head that is recessed a distance of 0.015 inch (0.38 millimeter) below the end cap and can move the sensing head a further 0.005 inch (0.12 millimeter) against a 0.5-pound (2.2-newton) force of a return spring, the point shall be identified as sharp. A sharp point tester of the general configuration shown in figure 1 of this section or one yielding equivalent results shall identify a sharp point. In conducting tests to determine the presence of sharp points, the Commission will use the sharp point tester shown in figure 1 of this section and the accessibility probes designed as A or B in figure 2 of this section.

(2) *Procedure.* (i) The sample to be tested shall be held in such a manner that it does not move during the test.

(ii) Part of the test sample may need to be removed to allow the sharp point testing device to test a point that is accessible by the criteria of paragraph (c) of this section. Such dismantling of the test sample could affect the rigidity of the point in question. The sharp point test shall be performed with the point supported so that its stiffness approximates but is not greater than the point stiffness in the assembled sample.

(iii) Using the general configuration shown in figure 1 of this section, the adjustment and operation of the sharp point tester is as follows: Hold the sharp point tester and loosen the lock ring by rotating it so that it moves towards the indicator lamp assembly a sufficient distance to expose the calibration reference marks on the barrel. Rotate the gaging cap clockwise until the indicator lamp lights. Rotate the cap counterclockwise until an equivalent of five divisions (the distance between the short lines on the cap) have passed the calibration reference mark. Lock the gaging cap in this position by rotating the lock ring until it fits firmly against the cap. Insert the point into the gaging slot in all directions in which it was accessible by the criteria of paragraph (c) of this section, and apply a force of 1.00 pound (4.45 newtons). A glowing light identifies the point as sharp.

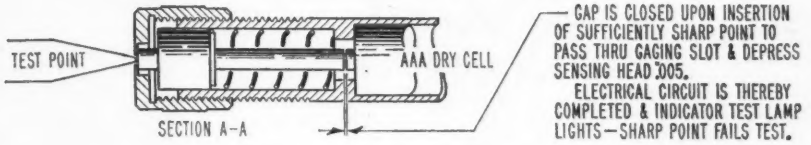
(iv) The test instruments used by the Commission in its tests for compliance with this regulation shall have gaging slot opening dimensions no greater than 0.040 inch by 0.045 inch and shall have the sensing head recessed a depth of no less than 0.015 inch. The force applied by the Commission when inserting a point into the gaging slot shall be no more than 1.00 pound.

(e) For the purpose of conformance with the technical requirements prescribed by this § 1500.48, the English figures shall be used. The metric approximations are provided in parentheses for convenience and information only.

(Secs. 2(s), 10(a), 74 Stat. 378 (15 U.S.C. 1261, 1269).)

Dated: December 16, 1977.

RICHARD E. RAPPS,
Secretary, Consumer Product Safety Commission.


TEST POINT
AAA DRY CELL
SECTION A-A
GAP IS CLOSED UPON INSERTION OF SUFFICIENTLY SHARP POINT TO PASS THRU GAGING SLOT & DEPRESS SENSING HEAD .005.
ELECTRICAL CIRCUIT IS THEREBY COMPLETED & INDICATOR TEST LAMP LIGHTS—SHARP POINT FAILS TEST.

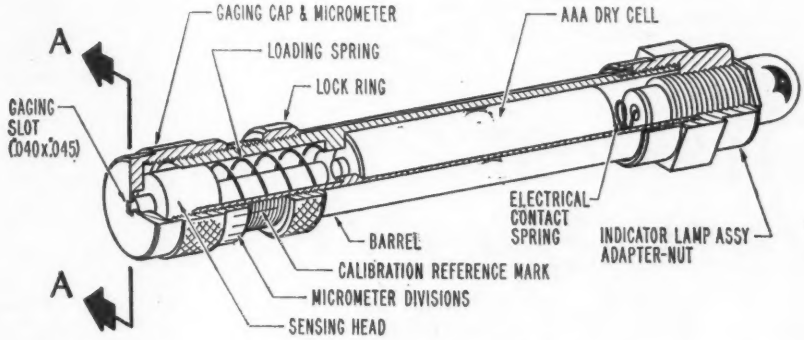
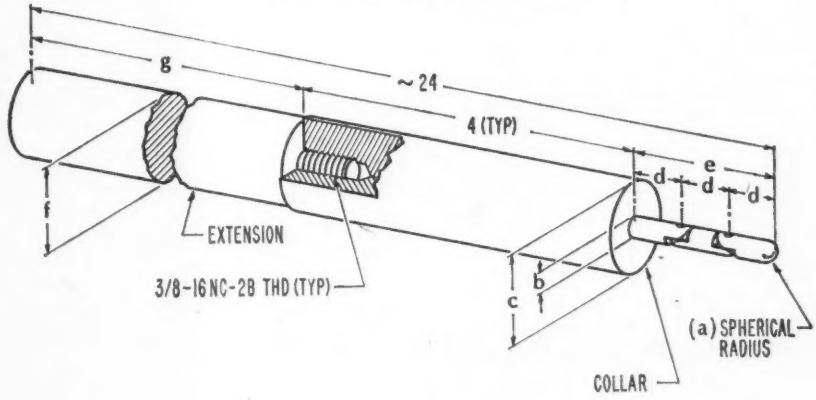


FIG 1—SHARP POINT TESTER



		a	b	c	d	e	f	g
(CHILDREN 0-36 MONTHS INCL)	PROBE A	.110	.220	1.020	.577	1.731	1	18 9/32
(" 37-96 " ")	PROBE B	.170	.340	1.510	.760	2.280	1 1/2	17 25/32

ALL DIMENSIONS IN INCHES

FIG 2—ACCESSIBILITY PROBES

[FR Doc.77-36487 Filed 12-21-77;8:45 am]